

10/549321  
JCS Rec'd PCT/PTO 16 SEP 2005

Docket No.: 0425-1214PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Tatsuo HORIZOE

Application No.: NEW

Confirmation No.: N/A

Filed: September 16, 2005

Art Unit: N/A

For: CONCOMITANT DRUG AS THERAPEUTIC  
AGENT FOR INFLAMMATORY BOWEL  
DISEASE

---

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Copies of the references on the PTO/SB/08 are not provided.

**10/549321**

Application No.: NEW

Docket No.: 0425-1214PUS1

**JC05 Rec'd PCT/PTO 16 SEP 2005**

Those documents which are marked with a double asterisk (\*\*) next to the Cite No. in the attached form PTO/SB/08 (facsimile) are not supplied because they were previously cited by or submitted to the Office in a prior application number PCT/JP2004/0003662, filed March 18, 2004.

A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

10/549321

Application No.: NEW

Docket No.: 0425-1214PUS1

JC05 Rec'd PCT/PTO 16 SEP 2005

Dated: September 16, 2005

Respectfully submitted,

By 

John W. Bailey

Registration No.: 32,881

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Rd

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|  |   |    |   |                          |                    |
|--|---|----|---|--------------------------|--------------------|
| Substitute for form 1449A/B/PTO  |   |    |   | <b>Complete if Known</b> |                    |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |   |    |   | Application Number       | NEW 10/549321      |
|  |   |    |   | Filing Date              | September 16, 2005 |
|  |   |    |   | First Named Inventor     | Tatsuo HORIZOE     |
|  |   |    |   | Art Unit                 | N/A                |
|  |   |    |   | Examiner Name            | Not Yet Assigned   |
| Sheet  | 1 | of | 1 | Attorney Docket Number   | 0425-1214PUS1      |

| U.S. PATENT DOCUMENTS |                       |   |                                |  |   |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       | AA                    | US-2004/102634-A1   | 05-27-2004                     | MATSUURA et al.                                    |   |

| FOREIGN PATENT DOCUMENTS |                       |   |                  |   |   |                |
|--------------------------|-----------------------|---|------------------|---|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) | MM-DD-YYYY       |   |   |                |
|                          | BA**                  | WO-02/100812-A  | 12-19-2002       |   |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\* CITE NO.: Those document(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | CA**                  | James D. Lewis et al., The American Journal of Gastroenterology, Vol. 96, No. 12, pages 3323, 2001  |                |
|                                 | CB**                  | Hitoshi ASAKURA, Igaku no Ayumi, Vol. 178, No. 9, pages 519 to 522, 1996  |                |
|                                 | CC**                  | Akihiro MUNEKATA et al., Igaku no Ayumi Vol. 178, No. 9, pages 491 to 495, 1996   |                |
|                                 | CD**                  | Tadao BABA et al., Igaku no Ayumi, Vol. 178, No. 9, pages 496 to 501, 1996  |                |
|                                 | CE**                  | Pierre Desreumaux et al., J. Exp. Med., Vol. 193, No. 7, pages 827 to 838, 2001   |                |
|                                 | CF**                  | Chinyu G. Su., J. Clin. Invest., Vol. 104, pages 383 to 389, 1999   |                |
|                                 | CG**                  | Cancer Research, Vol. 61, pages 2424 to 2428, 2001  |                |
|                                 | CH**                  | N. MATSUHASHI et al., LANCET, Vol. 358, pages 75 to 76, 2001  |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\* CITE NO.: Those document(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

Birch, Stewart, Kolasch &amp; Birch, LLP

JWB/smt